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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,514	05/30/2006	Adrian Hill	ISI-100	6383
23557 7590 01/07/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER				
SNYDER, STUART				
ART UNIT		PAPER NUMBER		
1648				
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01/07/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,514

**Applicant(s)**

HILL ET AL.

**Examiner**

STUART W. SNYDER

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-88 is/are pending in the application.
- 4a) Of the above claim(s) 65-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-64 and 80-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### ***Status of the Claims***

1. Amendment of previously presented claims 58, 63, 64, and 80 and addition of new claims 81-88 in Applicants' filing of 8/20/2008 is acknowledged. Claims 58-88 are pending; claims 65-79 are withdrawn.

#### ***Election/Restrictions***

2. With respect to the instant Examination, the claims are examined in view of Applicants' election of: MVA as the capsid and *M. Tuberculosis* as antigen.

#### ***Drawings***

3. The drawings were received on 8/20/2008. These drawings are accepted. Objection to the Drawings is **withdrawn** in view of Drawings amendments.

#### ***Specification***

4. Objection to the Abstract is withdrawn in view of Applicants' amendment filed 8/20/2008.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 58-64 and 80-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. The claims recite "A composition of matter comprising a) a viral capsid incapable of replication...". The Examiner notes that with respect to the instant rejection, that MVA—the elected capsid species—is fully capable of replication in at least CEF cells (see, for example, Feng, et al., p. 570, Materials and Methods, Construction of recombinant vaccinia viruses). As one of the preferred (and elected) embodiments of the invention, such a virus capsid can not be considered to be "incapable of replication" nor have Applicants presented a method to render MVA "incapable of replication". Thus, the specification as filed does not enable a skilled artisan to practice the invention and the claims are properly rejected under 35 U.S.C. 112, first paragraph.

6. Claims 58-64 and 80-88 are rejected 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "A composition of matter comprising a) a viral capsid incapable of replication...". The Examiner notes that with respect to the instant rejection, that MVA—the elected capsid species—is fully capable of replication in at least CEF cells (see, for example, Feng, et al., p. 570, Materials and Methods, Construction of recombinant vaccinia viruses). As one of the preferred (and elected) embodiments of the invention, such a virus capsid can not be considered to be

"incapable of replication" nor have Applicants presented a method to render MVA "incapable of replication". Thus, the specification as filed does not teach a skilled artisan the invention and the claims are properly rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Rejection of claims 58-64 and 80 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of amendments to claims 58, 63, 64, and 80.
8. Rejection of claim 64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of Applicants' arguments.
9. Rejection of claim 63 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of amendment of the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 58-64 and 80 stand rejected under 35 U.S.C. 102(b) as being anticipated by Feng, et al. Applicant's arguments filed 8/20/2008 have been fully considered but they are not persuasive. Applicants' arguments consist of a declaratory statement, "Feng et al. do[es] not teach a composition comprising a viral capsid incapable of replication and at least one protein antigen against which it is desired to obtain an immune response and that is co-administered with said capsid, said composition inducing both an antibody response against the co-administered protein antigen and a protective T-cell response against said co-administered protein antigen." However, as previously held by the Office, Feng, et al. teaches induction of simultaneously a CD8+ T-cell (see results and discussion) and an antibody response (see results, Table 1, page 572) to *M. tuberculosis*-encoded early secreted protein MPT64 under various immunization protocols including various pulse-chase procedures (see especially Figure 4, page 572 and figure 5, page 573) and the B-cell response being greater when the vector is MVA (see Figure 2, page 571). Furthermore, Feng, et al. teaches that CD8+ T-cell activation is associated with protection and that the antigens used in their studies activated such T-cell association (see Introduction and throughout). Thus each and every limitation of claims 58-64 and 80 are taught by Feng, et al. which clearly anticipates the instantly claimed invention and the rejection of the claims is **maintained**.

#### ***Conclusion***

11. No claims are allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **STUART W. SNYDER** whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Bruce R. Campell** can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS